



<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/857,012	CARO ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 July 2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3,5,6,12-16,24-31 and 42 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,5,6,12-16,24-31 and 42 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

***Election/Restrictions***

Claims 32-41 had been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Now, these claims were cancelled by the amendment filed July 15, 2004. Election was made **without** traverse in Paper No.7 filed December 1, 2003.

***Oath/Declaration***

The declaration filed July 15, 2004 is acceptable and has overcome the objection previously made.

***Double Patenting***

The double patenting rejection of the previous Office action has been withdrawn as a result of the terminal disclaimer filed July 15, 2004.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 42 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim language claims a combination of a stent with a naturally occurring article (i.e. an intact vessel). For this reason, the claim is considered non-statutory.

***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 24, 25, and 42 are rejected under 35 U.S.C. 102(b) as anticipated by Caro (WO 95/09585). Caro anticipates the claim language where the stent with supporting part as claimed is met by the shaped vascular prosthesis that includes "a stent or other structural support of plastic, metal or other material"; see the abstract and page 5, line 28 to page 6, line 10. This shaped tube of Caro especially with a metal stent therein would inherently impose a shape on a vessel it is inserted into because it is designed to be rigid enough to prevent kinking or collapse. The tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30.

Regarding claim 25 specifically, the tube of Caro is shaped but can be subject to collapse or kinking if not supported. Therefore, if the Examiner's position that flexing to some extent is inherent in Caro because it is made with a material that may kink or collapse without support. Furthermore, virtually all materials have at least some slight elastic deformation properties.

Regarding claim 42, the stent of Caro can be outside the tube such that it "internally supports" the blood vessel it is inserted into.

Claims 6 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 95/09585) in view of Fischell et al (US 5,697,971). Caro meets the claim language as set forth above but fails to disclose the type of stent claimed. However, Fischell teaches that the claimed stent was known to the art; see Figure 2 and Column 2, line 37 to Column 3, line 22. Therefore, it is the Examiner's position that it would have been obvious to use the Fischell stent as the stent of Caro because it would provide a means to prevent collapse and kinking as is the desire of Caro.

Regarding claim 26, the stainless steel of Fischell is an alloy of iron and chromium. It has shape memory in that it retains the shape it is expanded to; see column 2, lines 36-46.

Regarding claims 28-30, the links as claimed are met by elements (16) of Fischell.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 6 and 26-30 above, and further in view of Wolff (US 5,104,404). Caro as modified by Fischell has a stent with wave-shaped links but lacks the coil structure as claimed. However, Wolff teaches that it was known to make links with coil shapes; see Figure 3. Therefore, it would have been obvious to form the links of Caro as modified by Fischell into a coil form for the same reason as Wolff and since such coils would result in a great deal of flexibility between the "rings."

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 3, 5, 24, and 25 above, and further in view of Schwartz et al (6,015,387). Caro fails to disclose the monitoring device as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor, which must have a power supply and recording means to function. This is necessary because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*.

#### ***Response to Arguments***

In response to the argument that prosthesis of Caro is not necessarily capable for use as a stent, the Examiner asserts that the device of Caro clearly is capable of use as such because it is supported by a stent to prevent kinking or collapse. Furthermore, it would be improper for the Examiner to read "stent" of the present claims as precluding the additional structure that Caro includes.

In response to the argument that Caro is not capable of imposing a shape on a vessel, the Examiner asserts that the properties of the vessel have not been set forth such that the "vessel" fails to imply or infer any structure on the stent. Additionally, the tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery

and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30.

The Examiner has withdrawn the Section 103 portion of the first prior art rejection because it was not needed and because it did not properly state that Fischell was a teaching reference. Furthermore, the Examiner would like to state that the previous rejection in no way admitted that the Section 102 rejection was not tenable. Rather, the Examiner merely used two different interpretations of the claim language to formulate two different rejections.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738